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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/820,788	03/30/2001	Wei Shao	CL001207	3535

7590 10/02/2003

CELERA GENOMICS CORPORATION
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EXAMINER	
SCHNIZER, RICHARD A	

ART UNIT	PAPER NUMBER
1635	8

DATE MAILED: 10/02/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/820,788	SHAO ET AL.	
	Examiner	Art Unit	
	Richard Schnizer, Ph. D	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on *30 March 2001* .

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☐ Claim(s) *1-23* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) *1-23* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1, 2, 20, 21 drawn to a peptides comprising at least a portion of SEQ ID NO:2, or variants thereof, classified in class 530, subclass 306.

II. Claim 3, drawn to an antibody that recognizes a peptides comprising at least a portion of SEQ ID NO:2, or variants thereof, classified in class 530, subclass 387.1.

III. Claims 4, 5, 8-11, 13, 22, and 23 drawn to isolated nucleic acids, vectors, host cells, and a method of making a protein, classified in class 435, subclass 69.1.

IV. Claim 6, drawn to a gene chip, classified in class 435, subclass 287.2.

V. Claim 7, drawn to a transgenic animal, classified in class 800, subclass 13.

VI. Claim 12, drawn to a method of detecting a peptide by contacting the peptide with a detection agent, classified in class 435, subclass 6.

VII. Claims 14 and 15, drawn to methods of modulating the activity of a peptide, classified in class 435, subclass 4.

VIII. Claims 16 and 17, drawn to methods of identifying an agent that binds a polypeptide, and an agent so identified, classified in class 435, subclass 7.1.

IX. Claim 18, drawn to a method of treating a disease or condition by administering an unknown and physically undescribed agent, classified in class 514, subclass 1.

X Claim 19 drawn to a method of identifying a modulator of gene expression, classified in class 435, subclass 4.

The inventions are distinct, each from the other because of the following reasons:

The peptides of group I are related to the antibodies of group II because the peptides can be used for the production of the antibodies. The peptides are a distinct invention because they can be used in other processes which are materially different from the production of antibodies. For example, the polypeptides can function as pharmaceutical compositions. Further, a protein and its cognate antibody are structurally and functionally distinct molecules with different amino acid compositions.

The peptides of group I are related to the polynucleotides of group III and the gene chip of group IV because the polynucleotides of these groups encode the peptides. The polynucleotides have utility for the recombinant production of the protein in a host cell. Although the polynucleotides and the peptides are related, they are distinct inventions because the peptide products can be made by other and materially distinct processes, such as synthetic organic chemistry. Further, polynucleotides can be used for processes other than the production of peptides, such as nucleic acid hybridization assays.

The peptides of group I is related to the transgenic animal of group V because the transgenic animal can be used to produce the peptide. The inventions are distinct

because the peptides can be made by other and materially distinct processes, such as synthetic organic chemistry.

The peptides of group I are related to the methods of groups 6-8 as a product to processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the peptides can be used in methods of detoxifying drugs.

The peptides of group I are unrelated to the methods of groups 9 and 10. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the peptides of group I are not disclosed as an agents that bind themselves, nor as modulators of gene expression, and have different modes of operation, functions, and effects.

The antibodies of group II are related to the polynucleotides of group III and the gene chip of group IV only to the extent that these polynucleotides encode the cognate antigens of the antibodies. However, the polynucleotides are not directly necessary for antibody production, and the polynucleotides and antibodies are wholly different compounds having different compositions and functions. Therefore, these inventions are distinct.

The antibodies of group II are unrelated to the transgenic animal of group V. Inventions are unrelated if it can be shown that they are not disclosed as capable of use

together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the antibodies of group III cannot be used to produce the transgenic animal of group V, and are not produced by the animal These compositions are not disclosed as capable of use together and have different modes of operation, functions, and effects.

The antibodies of group II are related to the methods of groups VII-X because the antibodies could be used in, or identified by, these methods. Products and methods of use are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). Products and methods of making the products can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In this case, the inventions are distinct because the methods could use or identify reagents other than antibodies. For example, nucleic acid aptamers that specifically bind and/or inhibit the activity of the peptides of group I could be used to detect the peptides, as required by group VI, to modulate the activity of the peptides as required by group VII, could be identified by the assays of group VIII, and could be used as agents in the treatment method of group IX.

The isolated nucleic acids of group III are related to the gene chip of group IV, and the transgenic animal of group V because they can be used to construct the gene

chip and the animal. The inventions are distinct because they are functionally and structurally distinct compositions of matter. For example, the free nucleic acids can be used for polypeptide synthesis or the inhibition of gene expression as antisense molecules, whereas the immobilized nucleic acids of the gene chip will not function in these methods. Furthermore the nucleic acids can be used in hybridization assays, whereas the transgenic animal cannot.

The isolated nucleic acids of group III are unrelated to the methods of groups VI-IX. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the methods relate to detecting peptides, identifying modulators of peptides, binding peptides, and administering agents that bind a peptide. The specification does not disclose the claimed nucleic acids as being of direct usefulness in any of these methods.

The isolated nucleic acids of group III are related to the method of identifying a modulator of gene expression of group X as a product and a process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the nucleic acid could be used in a materially different process such as a hybridization probe in gene cloning, and the process can be performed with a materially different product such as a nucleic acid encoding the promoter that is naturally associated with

the gene from which SEQ ID NO: 1 was derived linked to a reporter gene such as luciferase.

The gene chip of group IV is unrelated to the inventions of groups V-X. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the gene chip and the transgenic animal have different modes of operation, functions, and effects, and are not disclosed as capable of use together. The specification does not disclose that the gene chip can be used in, or produced by the methods of groups VI-X. For example, gene chips are generally used in hybridization assays, but none of the recited methods discloses any hybridization step.

The transgenic animal of group V is unrelated to the inventions of groups VI-X. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01. The specification does not disclose that the transgenic animal can be used in, or produced by the methods of groups VI-X.

The methods of groups VI-X are unrelated. Each of these methods recites different method steps and achieves a different outcome. As such, the methods have different modes of operation, different functions, and different effects. Furthermore, the specification does not disclose use of the methods together in a single method.

Because these inventions are distinct for the reasons given above, have acquired a separate status in the art as shown by their different classification and their

recognized divergent subject matter, and because each invention requires a separate, non-coextensive search, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

Any inquiry concerning this communication or earlier communications from the examiner(s) should be directed to Richard Schnizer, whose telephone number is 703-306-5441. The examiner can normally be reached Monday through Friday between the hours of 6:20 AM and 3:50 PM. The examiner is off on alternate Fridays, but is sometimes in the office anyway.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John Leguyader, can be reached at 703-308-0447. The FAX numbers for art unit 1632 are 703-308-4242, and 703-305-3014. Additionally correspondence can be transmitted to the following RIGHTFAX numbers: 703-872-9306 for correspondence before final rejection, and 703-872-9307 for correspondence after final rejection.

Inquiries of a general nature or relating to the status of the application should be directed to the Patent Analyst Trina Turner whose telephone number is 703-305-3413.

DAVE T. NGUYEN
PRIMARY EXAMINER

Richard Schnizer, Ph.D.